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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/951,188	10/15/97	PRICE	IOWA-0127F05

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EXAMINER
LUNG, P

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 01/05/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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Office Action Summary

Application No.
08/951,188

Applicant(s)

Price

Examiner

Peter Tung

Group Art Unit

1652



☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-32 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-32 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Election/Restriction

1. Applicant's election without traverse of Group I, claims 1-32 in Paper No. 7 is acknowledged.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
4. The term "substantially full length" in claims 1, 2, 4-6, 11, 15, 23 and 31 is a relative term which renders the claim indefinite. The term "substantially full length" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear what would be considered a substantially full length P-TEFb or coding region. Removing "substantially full length" would correct the problem.

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5. Claims 3, 7-10, 12-14, 16-22, 24-30 and 32 are indefinite because they depend upon an indefinite base claim and fail to correct the problem.

6. Claim 19 recites the limitation "said DNA segment encoding a P-TEFb subunit fusion protein" in the last portion of the claim. There is insufficient antecedent basis for this limitation in the claim.

7. The term "stringent hybridization conditions" in claims 1, 4, 5 and 11 is a relative term which renders the claim indefinite. The term "stringent hybridization conditions" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The results obtained for a hybridization performed under "stringent hybridization conditions" would be dependent upon what specific conditions are used in the hybridization.

8. Claims 2, 3, 6-10, 12-22 and 27-32 are indefinite because they depend upon an indefinite base claim and fail to correct the problem.

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1, 4-6 and 23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a DNA encoding a P-TEFb large subunit comprising SEQ ID NOs: 4, 45, 47 or 50, does not reasonably provide enablement for a DNA encoding a P-TEFb large subunit comprising a contiguous sequence of at least 7 amino acids of SEQ ID NOs: 4, 45,

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47 or 50. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The breadth of the claim encompasses any naturally occurring or engineered P-TEFb large subunit that has at least 7 contiguous amino acids of the listed SEQ ID NOs. No guidance is provided on how to obtain or identify a P-TEFb based only upon at least 7 contiguous amino acids. No guidance is provided on which amino acid residues are enzymatically important in the large subunit of P-TEFb. Such guidance is necessary in order to make and use a P-TEFb which comprises only 7 contiguous amino acids of SEQ ID NOs: 4, 45, 47 or 50. No working examples of an enzymatically active large subunit of P-TEFb comprising only 7 contiguous amino acids of SEQ ID NOs: 4, 45, 47 or 50 are provided besides SEQ ID NOs: 4, 45, 47 and 50. Working examples would provide guidance on where substitutions in the sequences can be made where only 7 contiguous amino acids of SEQ ID NOs: 4, 45, 47 or 50 are present and still have an enzymatically active P-TEFb.

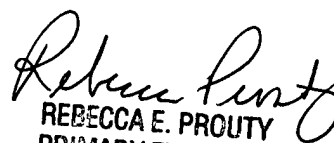
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Allowable Subject Matter

11. Claims 1-32 are allowable over the prior art of record.
12. No claims are allowed.
13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter Tung, Ph.D. whose telephone number is (703) 308-9436. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached on (703) 308-4216. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


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1600